88-1044

Supreme Court, U.S.
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No.

IN THE

Supreme Court Of The United States

October Term, 1988

ASSOCIATION OF SEAT LIFT MANUFACTURERS, ET AL.,

Petitioners,

v.

OTIS R. BOWEN, SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

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QUESTIONS PRESENTED

Whether a Medicare Part B program carrier's failure to comply with the Part B provisions of the Social Security Act and implementing regulations in administering the program is insulated from judicial review. Specifically, whether this Court's holding in *Bowen v. Michigan Academy of Family Physicians,* 476 U.S. 667 (1986), can be interpreted as precluding judicial review pursuant to the federal question statute, 42 U.S.C.A. § 1331 (West Supp. 1988), over challenges to a Part B carrier's failure to comply with the Part B statute and implementing regulations.

PARTIES TO THE PROCEEDING

In addition to the Association of Seat Lift Manufacturers, petitioners include Halsom Home Care, Inc.* In addition to Otis R. Bowen, Secretary of Health and Human Services, respondents include Barbara J. Gagel, Regional Administrator of the Health Care Financing Administration, and Nationwide Mutual Insurance Company, the Medicare Part B carrier for the state of Ohio.

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* Petitioner Association of Seat Lift Manufacturers is an unincorporated association. Petitioner Halsom Home Care, Inc. has no parent companies, subsidiaries or affiliates.

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PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

The Association of Seat Lift Manufacturers, *et al.*, petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Sixth Circuit in this case.

OPINIONS BELOW

The decision of the court of appeals (App., *infra,* 1-17a) is reported at 858 F. 2d 308 (6th Cir. 1988). The decision of the district court (App., *infra,* 18-22a) is unpublished.

JURISDICTION

The judgment of the court of appeals was entered on September 23, 1988. The jurisdiction of this court is invoked pursuant to 28 U.S.C. § 1254(1).

STATUTES INVOLVED

Relevant provisions of the Social Security Act, 42 U.S.C. § 301 *et seq.*, and implementing regulations are reprinted at App., *infra*, 1-16b.

STATEMENT

1. This case involves federal question jurisdiction over a challenge to the interpretation and implementation of the Medicare Part B provisions of the Social Security Act and implementing regulations by private insurance companies or "carriers." These carriers contract with the Health Care Financing Administration ("HCFA") to administer Part B, which *inter alia* reimburses enrolled beneficiaries and, following assignment of a beneficiary's claim, a provider or supplier, for 80 percent of the "reasonable charge" for medically necessary outpatient physician's services and other medical goods and services including durable medical equipment. *See* 42 U.S.C.A. § 1395l(a)(West 1983 & Supp. 1988).

2. The court below, interpreting this Court's opinion in *Bowen v. Michigan Academy of Family Physicians ("Michigan Academy")*, 476 U.S. 667 (1986), has denied jurisdiction over petitioners' claim that Nationwide Mutual Insurance Company ("Nationwide"), the Ohio Part B carrier, failed to comply with the Part B statute and implementing regulations by adopting a particular methodology for determining the Part B reasonable charge for an item of durable medical equipment, the seat lift chair.[1]

3. In mid-1985, the HCFA and Nationwide became concerned that the standard methodologies for calculating Part B reasonable charges[2] based on actual, historical submitted charges

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[1] Seat lifts are medical devices which assist individuals, who are otherwise unable because of severe arthritis or neuromuscular disease, in rising from, or lowering themselves to, a seated position.

[2] The standard Part B reasonable charge calculation methodologies are: submitted charge; charge for comparable services; customary charge; prevailing charge; inflation-indexed charge; and lowest charge level. Each of these standard reasonable charge calculation methodologies is based on actual, historical submitted charges. *See generally* 42 C.F.R. §§ 405.501-405.511 (1987) (App. 6-15b).

might lead to excessive reimbursement for seat lift chairs in Ohio. HCFA and Nationwide apparently were concerned that an alleged lack of competition in the supply of seat lift chairs to Part B beneficiaries and recent increases in the prices submitted by suppliers under Part B would lead to a higher reasonable charge. Nationwide, therefore, utilized a nonstandard methodology to calculate the reasonable charge -- the "inherently reasonable" methodology, which is based upon factors other than actual, historical submitted charges. *See* 42 C.F.R. §§ 405.502(a)(7), (g) (1987) (App. 8-13b).

4. In calculating a reasonable charge using the inherently reasonable methodology, carriers are required to rely on factors that are "necessary and appropriate" and to consider "special factors that may exist in individual cases so that the calculation is realistic and equitable." *See* 42 C.F.R. §§ 405.502(a)(7), (c) (1987) (App. 8-9b). A carrier can, for example, consider suppliers' actual cost of providing seat lift chairs or the prices of seat lift chairs in sales to non-Medicare beneficiaries.[3]

5. Nationwide based the inherently reasonable charge for seat lift chairs solely on the very lowest price ever charged by any seat lift chair retailer in either the Ohio Medicare or Ohio non-Medicare markets -- the non-Medicare (*i.e.*, from a vendor which does not take Medicare assignment) price of the very cheapest of four seat lift chairs available from the Sears, Roebuck & Company ("Sears") mail order catalogue -- without consideration of the

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[3] Factors which a carrier may consider in establishing an inherently reasonable charge are set forth in Medicare Carriers Manual § 5246. The version of Section 5246 in effect when this action arose did not list mail order catalogue prices as an inherently reasonable factor. *See* Medicare Carriers Manual § 5246 (Rev. 1115 May 1977). Section 5246 was subsequently amended enumerating mail order catalogue prices as an inherently reasonable factor. *See* Medicare Carriers Manual § 5246 (Rev. 1125 Aug. 1985). Section 5246 was amended yet again in 1987, removing mail order catalogue prices as an inherently reasonable factor. *See* Medicare Carriers Manual § 5246 (Rev. 1180 Apr. 1987). No Part B carrier has ever relied on mail order catalogue prices as an inherently reasonable factor in setting the reasonable charge for any medical service or item of equipment other than seat lift chairs.

"necessary and appropriate" and "special" factors required by the reasonable charge regulations.

6. During the statutory period (April 1, 1984 through March 30, 1985) relevant to the reasonable charge determination at issue here, Sears sold less than six seat lift chairs in Ohio (Joint Appendix at 346a, Affidavit of Ann Stapleton) compared with 11,504 claims for reimbursement for seat lift chairs which were submitted to Nationwide under Part B (Brief of Defendants-Appellees at 15). There is no evidence in the record: (a) that any of the 94 suppliers (Brief of Defendants-Appellees at 17) who submitted Part B reimbursement claims during the relevant period actually sold a seat lift chair at anything close to the Sears mail order catalogue price; (b) that Sears could obtain from its manufacturer a sufficient volume of seat lift chairs to supply the Ohio Medicare market at that price; or (c) that the other suppliers which provided seat lift chairs in Ohio could afford to supply to Part B beneficiaries at the price charged by Sears.

7. The record reflects that mail order catalogue houses such as Sears have different cost structures from the vast majority of suppliers of durable medical equipment under Part B. Sears, for example, does not warehouse seat lift chairs, employ a staff to sell or service seat lift chairs, or accept assignment and process claims through the Part B system -- a time consuming and expensive process (Joint Appendix at 346a, Affidavit of Ann Stapleton).

8. At the time the HCFA and Nationwide became concerned that continued reliance on the standard reasonable charge methodologies might yield a significant increase in Part B reimbursement, the reasonable charge in effect in most of Ohio was $1,485 (Brief of Defendants-Appellees at 18 n.12). The Nationwide analyst reviewing that reasonable charge concluded that an alleged potential increase in the reasonable charge to $2,400 under the standard methodologies would justify resort to the non-standard inherently reasonable methodology. The analyst also concluded, however, that a reasonable charge of $1,695 would not "be substantially out of line" (Brief of Defendants-Appellees at 18). Despite this finding, Nationwide promulgated a reasonable

charge of $861.59 -- based on the very lowest price it could locate, the $749.95 Sears mail order catalogue price for its very cheapest seat lift chair.

9. Although Nationwide justified its resort to the non-standard inherently reasonable methodology on its conclusion that the Ohio Medicare market for seat lift chairs was "non-competitive", Nationwide did not compare pricing in the Ohio Medicare market with pricing in the non-Medicare market (Joint Appendix at 347a-428a, Deposition of Lanna Carruthers), which prices were in fact competitive. Pricing in the non-Medicare market, moreover, did not support the inherent reasonableness of relying on sales by Sears. Ortho-Kinetics, Inc., the manufacturer/retailer from which Sears purchased its cheapest seat lift chair, for example, sold virtually the same seat lift chair under its own label to non-Medicare beneficiaries at a price of $1,395 during the time period Sears sold its version for $749.95.

10. Nationwide's only benchmark for the inherent reasonableness of the Sears mail order catalogue price was to review wholesale prices, which Nationwide determined ranged from $450 to $850, and "suggested retail prices" for non-Medicare sales, which Nationwide determined ranged from $995 to $1,995. Nationwide, however, failed to consider any suppliers' costs in selling seat lift chairs beyond wholesale equipment acquisition cost (Joint Appendix at 347a-428a, Deposition of Lanna Carruthers). Nationwide, therefore, had no basis to know what retail markup above wholesale costs was fair and reasonable. The manufacturer whose $995 purported price was the lowest suggested retail price relied upon, moreover, denied that it ever set a suggested retail price (Joint Appendix at 344a, Affidavit of Joseph O'Brien).

11. Nationwide promulgated the inherently reasonable charge for seat lift chairs in Ohio on July 10, 1985 without any opportunity for formal public comment or even informal input from affected beneficiaries or suppliers. The effective date was August 19, 1985.

12. On August 12, 1985, one week prior to the date the inherently reasonable charge was to become effective in Ohio,

petitioners filed suit in the United States District Court for the Northern District of Ohio challenging Nationwide's action. Petitioners allege that Nationwide utilized a methodology which violated the reasonable charge regulations because it resulted in an allowable that was neither appropriate, realistic nor equitable as required by 42 C.F.R. §§ 405.502(a)(7),(c)(1987). Petitioners also allege that Nationwide failed to consider "special factors," as required by 42 C.F.R. § 405.502(c)(1987), or certain relevant factors as required by the Administrative Procedure Act, 5 U.S.C.A. § 706(2)(A)(West 1977)(App. 5-6b). Finally, petitioners allege that Nationwide's reliance on the very lowest price available in a relevant market violated HCFA policy, expressed in an earlier rulemaking, *see* 43 *Fed. Reg.* 32294, 3295-96 (July 26, 1978), that it would be inappropriate to use the very lowest price available in promulgating a reasonable charge.

13. Nationwide's inherently reasonable charge had adverse consequences for seat lift chair manufacturers and suppliers, including lost sales, lost profits and discharged employees (Joint Appendix at 464a-494a).

14. While this action was pending before the district court, this Court decided *Michigan Academy.* The district court, interpreting *Michigan Academy*, determined that there was no jurisdiction and dismissed the action.

15. The U.S. Court of Appeals for the Sixth Circuit affirmed the dismissal for lack of jurisdiction, making three conclusions of law: (a) only challenges to the Part B statute and implementing regulations are within the federal question jurisdiction; challenges to a Part B carrier's interpretation and implementation of the same Part B statute and implementing regulations are not; (b) challenges to a Part B carrier's interpretation and implementation of the reasonable charge methodology regulations are not challenges to the "methodology" of a benefit determination cognizable under the federal question jurisdiction, but rather constitute challenges to an amount of benefits determination, which are not; and (c) the availability of federal question jurisdiction is not dependent upon whether a claim challenges an amount of benefits determination,

but rather upon whether the claim can be heard by a carrier hearing officer.

REASONS FOR GRANTING THE PETITION

In *Michigan Academy*,[4] this Court clearly held that there was no congressional intent to insulate the Medicare Part B provisions of the Social Security Act and implementing regulations from judicial review. The decision below eviscerates *Michigan Academy* by employing a judicial slight of hand -- the disingenuous conclusion that only an individual benefit amount is at issue -- to avoid a troublesome case. The decision below, if allowed to stand, would permit the HCFA to implement sweeping programmatic and methodology decisions without challenge. It would allow the HCFA and the carriers to shield their administration of Part B from judicial scrutiny by the simple expedient of enacting valid regulations but then ignoring those very regulations, secure in the knowledge that their actions are insulated from judicial review. The ultimate consequence of allowing a carrier to peg Part B reimbursement at artificially and unrealistically low levels contrary to the Part B statute and implementing regulations is that America's aged infirm will be unable to obtain needed medical equipment and services from suppliers unable either to provide it economically or to challenge effectively the administrative decision which produced that circumstance. The decision below is an unduly restrictive interpretation of *Michigan Academy's* liberal jurisdictional test[5] and in square conflict with decisions in other circuits. "[A]cceptance of the [Sixth Circuit's] position would 'make a

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[4] *Michigan Academy* is one of a trio of recent decisions of this Court which have rejected the Medicare administrators' persistent efforts to insulate their activities from judicial review. *See Bowen v. Massachusetts*, ___U.S.___, 108 S. Ct. 2722 (1988); *Bethesda Hospital Ass'n. v. Bowen*, ___ U.S. ___, 108 S. Ct. 1255 (1988).

[5] The issue of drawing the jurisdictional distinction between a challenge to an individual amount of benefits determination and a challenge to the methodology on which it is based is also the subject of a pending Petition for a Writ of Certiorari to the United States Court of Appeals for the Second Circuit in the case of *Kuritzky v. Blue Shield of Western New York, Inc.*, No. 88-685.

mockery . . . of [due process],' since 'agencies would be free to violate [their own regulations] with impunity if, upon [issuance] of a rule, they were free to' [ignore] 'that rule . . .'" *Bowen v. Georgetown University Hospital*, 57 U.S.L.W. 4057, 4063 (Dec. 12, 1988) (Scalia, J., concurring).

A. The Conflict Among the Circuits

The decisions of at least seven federal courts in five circuits which have considered claims that a Part B carrier failed to comply with the Part B statute and implementing regulations in administrating the program are inconsistent with the decision below. Courts in the First, Second, Third, Fifth and District of Columbia Circuits considering challenges to the adminstration of the Part B program other than challenges to the Part B statute or implementing regulations, have found federal question jurisdiction.

In *McCuin v. Secretary of Health and Human Services,* 817 F. 2d 161, 165 (1st Cir. 1987), a Medicare Part A case determined by the First Circuit to involve jurisdictional issues identical to Part B, the First Circuit found jurisdiction over a challenge "to the Secretary's interpretation of the [Part A] regulations."

In *Medical Fund-Philadelphia Geriatric Center v. Heckler,* 804 F. 2d 33, 39 (3rd Cir. 1986), the Third Circuit held that an "allegation, which . . . challenges [the] lawfulness [of a policy] as applied . . ." can be reviewed by a federal court.

In *Griffith v. Bowen,* 678 F. Supp. 942, 944 (D. Mass. 1988), the district court found jurisdiction over an action "to review the manner or method by which the Secretary implements the Medicare Part B program . . ."

In *Integrated Generics, Inc. v. Bowen,* 678 F. Supp. 1004, 1008 (E.D. N.Y. 1988), the district court found jurisdiction over the plaintiff's challenge, *inter alia,* to the government's "compliance with existing regulations."

In *Health Industry Distributors Association v. Bowen,* Medicare and Medicaid Guide (CCH) ¶ 36,748, 15,709 (D.D.C. Oct. 8, 1987), the district court found jurisdiction over plaintiff's

"challenge . . . to the methodology underlying the Secretary's determination of Medicare reimbursement."

In *Quality Care Medical Equipment Co., Inc. v. Bowen*, Misc. No. 88-0572, slip op. at 14 (E.D. Pa. Nov. 16, 1988), the district court held that carriers:

> have an obligation to implement the Medicare Part B program consistently with the statute . . . [and that this] Court concluded in *Michigan Academy* [that] Congress has not precluded judicial review to ensure that such mandate is met. Challenges to the [carriers'] process based on the statute and the constitution are thus within the subject matter jurisdiction of the federal courts."

In *Texas Medical Ass'n v. Bowen*, 678 F. Supp. 643, 648 (W.D. Tex. 1988), the district court exercised jurisdiction over plaintiff's claim "that the carrier's use of a statewide fee schedule for eighteen Medicare Part B procedures [*i.e.*, a particular interpretation of the carrier's reasonable charge determination authority] was improper."

These seven decisions confirming federal question jurisdiction conflict not only with the court of appeals below, but also with the interpretation of *Michigan Academy* by the Second Circuit in *Kuritzky v. Blue Shield of Western New York, Inc.*, 850 F.2d 126, 128 (2nd Cir. 1988)(pending petition for writ of certiorari, No. 88-685), a decision cited by the court below, holding that the:

> distinction that emerges from [*United States v.] Erika* and *Michigan Academy* is that federal [question] jurisdiction exists where there is a [facial] challenge to the validity of an agency rule or regulation [citations omitted], but jurisdiction is lacking where the claim is merely that the [Part B] carrier misapplied or misinterpreted valid rules and regulations [citations omitted].

In addition, in *Mobile Medical Services, Inc. v. Arkansas Blue Cross and Blue Shield*, 676 F. Supp. 194, 197 (W.D. Ark. 1987), the district court denied jurisdiction because plaintiffs "chal-

leng[ed] . . . not the validity of a statutory provision or a regulation but instead the finding made by Blue Cross . . ." in implementing those provisions.

This Court should grant this petition to address these inconsistencies and to correct the misinterpretation of its liberal *Michigan Academy* jurisdictional test.

B. Federal Question Jurisdiction

1. When establishing the Medicare Part B program more than twenty years ago, Congress apparently recognized that controversies inevitably would be generated relating to specific individual benefit determinations and involving relatively modest sums. *See Michigan Academy*, *supra* at 674-78. Congress, apparently intending that the federal courts should not be burdened with such controversies, impliedly precluded judicial review by failing to provide jurisdiction pursuant to Section 1869 of the Social Security Act, 42 U.S.C.A. § 1395ff (West 1983 & Supp. 1985)(amended 1986, 1987)[6] (App. 1-2b). Congress provided as an alternative the limited form of administrative review embodied in the carrier review/fair hearing procedures.

Congress, however, perhaps not anticipating the substantial programmatic (rather than individual) controversies which have arisen in the administration of what is now the $70-billion-a-year Medicare program, failed specifically to provide for administrative review over challenges to the administration of Part B. Congress' omission left the lower federal courts without guidance as to which categories of Part B-related claims were excluded from judicial review by operation of Section 1395ff, and which categories were otherwise cognizable under the general federal question jurisdiction. 28 U.S.C.A. § 1331 (West Supp. 1988)(App. 1b). The sole

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[6] Section 205(h) of the Social Security Act, 42 U.S.C.A. § 405(h)(West 1983)(App. 1b), provides that claims relating to any Social Security program are cognizable by the federal courts only as provided by the Act and specifically precludes federal question jurisdiction "to recover on any claim." Section 1872 of the Social Security Act, 42 U.S.C.A. § 1395ii (West Supp. 1988)(App. 5b), makes Section 405(h) applicable to the Part B program.

early guidance was this Court's decision in *United States v. Erika*, 456 U.S. 201 (1982), which held only that Congress intended to preclude federal question jurisdiction over claims relating to specific, individual benefit amount determinations.

Recognizing that Congress had failed to address what had become an issue of surpassing national importance -- whether the federal courts could entertain challenges to the administration of the Part B program -- and that the decisions of the lower courts on this jurisdictional issue were wildly inconsistent, this Court two years ago issued its opinion in *Michigan Academy*, establishing a simple and predictable jurisdictional test. Based on an exhaustive review of the legislative history of the Part B statute in light of the strong presumption in favor of judicial review, this Court held that Congress intended only the following jurisdictional distinction: the enormous volume of challenges involving "minor matters", *i.e.*, individual benefit amount determinations, are relegated to administrative review; challenges implicating other matters are directly cognizable in district courts under the general federal question jurisdiction. This Court also held that the *Michigan Academy* plaintiffs' challenge to the methodology of a benefit amount determination was distinguishable from a challenge to a specific, individual determination of the amount of benefits due, and, thus, was cognizable under the federal question jurisdiction.

The rationale underlying *Michigan Academy* is manifest. Benefit amount determinations require highly specific, individualized fact finding with which Congress was loath to burden the federal judiciary. Challenges to the administration of Part B, in contrast, promote judicial economy by determining issues of general applicability on a programmatic rather than individual basis.

The practical consequences of this Court's liberal *Michigan Academy* jurisdictional test are: (a) claims relating solely to the amount of benefits due can be appealed through the two-step administrative review process (*i.e.*, carrier review and carrier fair hearing) and no further, and (b) all other (*i.e.*, programmatic)

claims can be brought directly before the federal courts without prior exhaustion of the administrative review process.[7]

2. The court below held that:

> *Michigan Academy* concluded that challenges to statutes, regulations, and instructions prescribing Part B payment criteria, rather than challenges to the application of such criteria by Carriers in making Part B "payment determinations," were the only type of challenge [which could be heard under the federal question jurisdiction].

(App. 14-15a). This action, like *Michigan Academy*, also involves a challenge to a Part B reasonable charge methodology, the only distinction being that where the *Michigan Academy* plaintiffs challenged the methodology facially, this action challenges the methodology "as applied," *i.e.*, the carrier's failure to comply with the Part B statute and implementing regulations. The court of appeals' restrictive interpretation -- that while facial challenges to the Part B reasonable charge provisions and implementing regulations are within the federal question jurisdiction, challenges to the

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[7] In 1986 Congress amended Section 1395ff to provide that actions arising after January 1, 1987 and relating exclusively to a specific, individual benefit amount determination (which under the *Michigan Academy* jurisdictional test had been relegated to the two levels of administrative review and precluded from federal court jurisdiction) could be appealed to the federal courts under the Social Security Act, but only following four levels of administrative review (*i.e.*, carrier review, carrier fair hearing, administrative law judge hearing, and Appeals Council review). 42 U.S.C.A. § 1395ff (West Supp. 1988)(App. 2-5b). Exhaustion of the four levels of administrative review preliminary to district court review, however, is enormously time consuming and expensive. For example, no claim under the new appellate procedure has yet been decided by (and may not even have reached) any district court in the more than 23 months such review has been available. Thus, the ability to appeal certain challenges (which like this action implicate issues other than amount of benefit determinations) directly to the district court under the federal question jurisdiction without resort to this protracted appellate process under the Social Security Act is of enormous importance to certain plaintiffs and essential to the timely litigation of what can be substantial issues involving the threat of serious irreparable injury. *See, e.g., Health Industry Distributors Ass'n v. Bowen, supra.*

carrier's interpretation and implementation of the same statute and regulations cannot be heard -- is fundamentally inconsistent with *Michigan Academy*.[8]

The jurisdictional dichotomy that this Court drew in *Michigan Academy* was not, as the court below held, between facial challenges to the Part B statute and implementing regulations on the one hand and all other challenges on the other, but rather between challenges to amount of benefit determinations on the one hand and all other challenges on the other. Where the legislative history reviewed extensively by this Court in *Michigan Academy* indicates a clear congressional purpose to preclude judicial review of the amount of individual benefit determinations, that history reflects no intention whatsoever regarding jurisdiction over claims challenging the administration of the Part B program, much less the clear and convincing evidence of legislative intent required to preclude federal question jurisdiction. *See Michigan Academy, supra* at 671-72, *citing Abbott Laboratories v. Gardner*, 387 U.S. 136, 141 (1967). *See also Bartlett v. Bowen, supra* n.8 at n.11 ("Supreme Court precedent could not be clearer that the burden falls on the government to show clearly and convincingly that Congress meant its judicial review provisions to preclude review of administrative action.")

The actual language of *Michigan Academy,* moreover, indicates that this Court did not hold that facial challenges to the Act or implementing regulations were the *only* type of challenge for which federal question jurisdiction existed. This Court stated:

> that those matters which Congress did not leave to be determined in a "fair hearing" conducted by the carrier

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[8] As the U.S. Court of Appeals for the District of Columbia Circuit recently stated:

> the logic of cases casting doubt on the constitutionality of denying a forum for the litigation of [facial challenges to a statute] would appear to apply with equal force to claims challenging the statute as applied [citation omitted].

Bartlett v. Bowen, 816 F. 2d 695, 701-02 n. 24 (D.C. Cir. 1987). *See Devine v. Cleland*, 616 F. 2d 1080 (9th Cir. 1980); *Ralpho v. Bell*, 569 F. 2d 607 (D.C Cir. 1977).

> -- *including* [but, obviously, not limited to] challenges to the validity of the Secretary's instructions and regulations -- are not impliedly insulated from judicial review . . . [and that] . . . matters which Congress did not delegate to private carriers, *such as* [but again, not only] challenges to the validity of the Secretary's instructions and regulations, are cognizable in courts of law. [emphasis added].

476 U.S. at 678 and 680. Merely by including statutory and regulatory challenges as *examples* of the category of claims for which Congress did not intend to preclude federal question jurisdiction, this Court did not mean that Congress intended to preclude jurisdiction over other types of challenges (except, of course, individual benefit amount determinations).

The manifest congressional intent behind the jurisdictional preclusion of Section 1395ff -- judicial economy -- is not served by the court of appeals' restrictive interpretation. Challenges to a carrier's interpretation and implementation of a reasonable charge methodology regulation do not implicate the highly specific, individualized factual determinations from which Congress sought to spare the federal judiciary. Challenges to a reasonable charge methodology regulation as applied, every bit as much as facially, have broad programmatic, rather that individual implications.

The court of appeals' restrictive interpretation, if left uncorrected, would establish a loophole in the liberal jurisdictional test of *Michigan Academy* which would subsume the whole. The HCFA and the carriers could circumvent judicial scrutiny by enacting eminently reasonable regulations and then interpreting and implementing those regulations in any way they chose, no matter how unreasonable.

3. The court below also held that:

> [b]ecause the instant plaintiffs essentially disputed only Nationwide's application of the "inherent reasonableness" criterion in determining the reasonable charge for

> seat lift chairs rather than the validity of that criterion itself, their so-called "method" challenge is actually a challenge to an amount determination and *Erika*, rather than *Michigan Academy* is controlling [citation omitted].

(App. 15a). The court of appeals' rather remarkable conclusion that a challenge to a carrier's interpretation and implementation of a reasonable charge methodology regulation is not in fact a "methodology" challenge in the *Michigan Academy* context is both oxymoronic and inconsistent with *Michigan Academy*, which recognized that all reasonable charge determinations implicate both the methodology used and the amount of benefits ultimately payable on reimbursement claims.[9] This Court distinguished (a) challenges which do not dispute that the reasonable charge methodology used was legal but which only claim that the amount determined was wrong, from (b) challenges, such as this action, which claim that the methodology utilized was illegal and do not even address the derivative issue of the correctness of the specific amount determined. This Court found jurisdiction over the latter category but not the former. Under the liberal *Michigan Academy* jurisdictional test, a federal court is not precluded from considering a challenge to a reasonable charge methodology as applied merely because the resolution of the issue ultimately would affect the amount of Part B benefits. *McCuin, supra* at 165 (This "Court has instructed us . . . to construe the word 'amount' narrowly");

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[9] As the court below has pointed out, an Ohio supplier not a party to this action utilized the administrative review process to challenge the application of the inherently reasonable charge methodology to certain of its specific reimbursement claims. That supplier raised only the issue of whether the amount it was paid on specific claims was correctly determined, alleging that it had incurred supplier-specific costs not reflected in the reasonable charge and that its benefits should be recalculated to reflect those supplier-specific costs. That supplier's allegations required precisely the sort of individualized fact finding that Congress intended to spare the federal judiciary. That supplier did not raise, nor did the carrier hearing officer consider, the issues implicated in this action -- that the Part B statute and regulations proscribe resort to a mail order catalogue price under certain circumstances as the basis for the calculation of an inherently reasonable charge with carrierwide applicability.

Medical Fund-Philadelphia Geriatric Center v. Heckler, supra at 39; *Texas Medical Ass'n v. Bowen, supra* at 643.

If the court of appeals' restrictive interpretation is allowed to stand, federal question jurisdiction would be limited to challenges brought by plaintiffs with no possible financial interest in the outcome, *i.e.*, individuals with no present or potential reimbursement claims. The practical effect of limiting jurisdiction solely to challenges brought by such implausibly altruistic plaintiffs would be to eliminate challenges to reasonable charge methodologies altogether.

4. The court below also held that challenges to a Part B carrier's interpretation and implementation of reasonable charge methodology regulations cannot be heard under the federal question jurisdiction because such challenges can be heard by carrier fair hearing officers (App. 16-17a). The court of appeals' rationale, however, both misinterprets this Court's holding in *Michigan Academy* and is an incorrect conclusion of law.

The jurisdictional distinction drawn in *Michigan Academy* was between challenges to specific, individual benefit amount determinations, for which there is no federal question jurisdiction, and all other challenges, for which there is. The relevant jurisdictional distinction is not between challenges which can be raised at a carrier fair hearing and challenges which cannot. Challenges to specific, individual benefit amount determinations are not precluded from federal question jurisdiction by virtue of the fact they can be raised before carrier hearing officers, but rather because Congress intended that the federal courts should not be so burdened. That specific, individual benefit amount determinations are heard by carrier hearing officers is a consequence, rather than the cause, of the preclusion of federal judicial review. Such claims have been relegated to hearing officers to provide the minimal constitutionally-mandated due process and to ensure that such claims are heard somewhere. Thus, whether a carrier hearing officer can hear a particular challenge is more properly viewed as a result of the jurisdictional inquiry, rather than as a determinant thereof.

The court of appeals' legal conclusion that challenges such as this action could be brought before hearing officers is incorrect. This action was brought prospectively, *i.e.*, before the reasonable charge at issue became effective. Petitioners do not claim that the amount was incorrectly calculated for any specific, individual claim for benefits, but rather that the reasonable charge, which had yet to be applied to *any* claim for reimbursement, had been promulgated by Nationwide illegally.[10] Because carrier hearing officers have jurisdiction only over specific, individual claims for benefits which have been processed for payment by the carrier, *see* 42 C.F.R. § 405.820 (a)(1987)(App. 15-16b), a carrier hearing officer by regulation could not exercise jurisdiction over petitioners' claims that the carrier had failed to comply with the Part B statute and regulations.

The court of appeals in determining that this action is within the jurisdiction of a carrier fair hearing officer also relied in part on the fact that the HCFA had not "instructed" Nationwide to follow a particular interpretation of a inherently reasonable charge methodology, thereby leaving a hearing officer free to reverse Nationwide pursuant to 42 C.F.R. § 405.860 (1987)(App. 16b). The court below characterized certain communications between the HCFA and Nationwide regarding the implementation of the inherently reasonable charge methodology as "purely informational."[11] However, even if purely informational rather than instructional, these communications represent a clear articulation

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[10] *See Health Industry Distributors Ass'n v. Bowen, supra* at 15,709 ("Plaintiffs have made a convincing showing in their pleadings and in oral argument that their challenge in this case is to the *methodology* underlying the Secretary's determination of Medicare reimbursement. This is underscored by the fact that plaintiffs are not here with vouchers to dispute individual reimbursement decisions but rather are representing a community of medical suppliers who have an interest in the method by which reimbursement calculations are made.")

[11] On May 30, 1985, the HCFA articulated its policy that "it would not be inherently reasonable to allow more than the [Sears catalogue price of] $749.95 plus shipping for the purchase of a seat lift chair . . ."(Joint Appendix at 319a-323a). In June 1985, the HCFA instructed Nationwide that "[i]t would not be inherently reasonable to allow more than such nationally available [mail order catalogue] prices (plus shipping) for the purchase of a seat lift chair . . ." (Joint Appendix at

of HCFA policy. The HCFA policy that it is not inherently reasonable for a reasonable charge to exceed the very lowest mail order catalogue price available is precisely what is at issue in this action. Under the regulations applicable to carrier fair hearings, a carrier hearing officer "may not . . . interpret . . ." "provisions of law in a way different than HCFA does . . ." Medicare Carriers Manual § 12016.A (Rev. 1135 Nov. 1985)(App. 16b). A carrier hearing officer, therefore, is not free to disagree with HCFA's expression of its policy regarding the implementation of the inherently reasonable charge methodology and could not exercise jurisdiction over this action.

If the decision below is allowed to stand, a practical consequence for plaintiffs whose causes of action (unlike this one) arise after the effective date of the 1986 amendment to Section 1395ff, which provides for judicial review of Part B-related challenges under the Social Security Act (rather than the federal question statute, *see supra* n.7), following four tiers of administrative review, is that actions such as this one likely will not come before a district court for a period of years. While the protracted administrative review procedure drags on, suppliers may be unable to provide services and equipment, and beneficiaries as a result may be denied medically necessary treatment. The prospect of such interminable delay assumes special significance in the context of Part B benefits ultimately accruing to beneficiaries who must by statute be over 65 years of age.

323a-324a). In an internal memo of June 28, 1985, the HCFA characterized its communications with Nationwide:

> We have issued a regional letter to all Region V carriers [including Nationwide] *directing* them to obtain catalogue prices for seat lifts and to reach a decision on inherent reasonableness...*Nationwide will prepare a draft notice to suppliers stating the inherently reasonable charge for seat lifts based on readily available [Sears] catalogue seat lift price.* We should get that draft next week and will clear it through regional OGC. The inherently reasonable amount should be about one-third lower than the amount Nationwide is now allowing. The new allowance will take effect 30 days after release of the notice [emphasis added].

(Joint Appendix at 326a-327a).

CONCLUSION

This petition for a writ of certiorari should be granted.

Respectfully submitted,

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December 1988.

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ASSOCIATION OF SEAT LIFT MANUFACTURERS, a trade association, Halsom Home Care, a corporation, and Hudson Home Health Care, Inc., a corporation, Plaintiffs-Appellants,

v.

Otis R. Bowen, Secretary of Health and Human Services, et al., Defendants-Appellees.

No. 87-3149.

United States Court of Appeals, Sixth Circuit.

Argued Jan. 15, 1988.

Decided Sept. 23, 1988.

Before ENGEL, Chief Judge*,

KENNEDY and KRUPANSKY, Circuit Judges.

KRUPANSKY, Circuit Judge.

This action arises under Title XVIII of the Social Security Act 42 U.S.C.A. § 1395 et seq., (West 1983) commonly referred to as Medicare (hereinafter Program) wherein the appellants seek to vacate a determination by Nationwide Mutual Insurance Company (Carrier), the Part B Ohio Medicare Carrier, fixing the allowable "reasonable charge" for a seat lift chair payable to Medicare beneficiaries under Part B of the Program in Ohio at $869.51. On January 30, 1987, the district court dismissed the action for lack of jurisdiction citing to the Supreme Court decision in *Bowen v. Michigan Academy of Family of Physicians,* 476 U.S. 667, 106 S.Ct. 2133, 90 L.Ed.2d 623 (1986) wherein it was held that Congress intended to bar judicial review of the "amount of benefits" to be awarded under Part B of the Program, which determinations were delegated to the Carrier acting in conformity with regulations and instructions of the Secretary.[1] The Court did not,

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*The Honorable Albert J. Engel assumed the duties of Chief Judge effective April 1, 1988.

1. The instant appeal is governed by 42 U.S.C.A. § 1395ff (West Supp. 1988), which in turn refers to 42 U.S.C.A. § 405(h) (West 1983). The latter provision reads as follows:

(h) Finality of Secretary's decision.

however, exclude from judicial review challenges to the validity of the Secretary's regulations, instructions, and to the methodology implemented in deriving the "amount of benefits." *See United States v. Erika,* 456 U.S. 201, 102 S.Ct. 1650, 72 L.Ed.2d 12 (1982). Part B of the Program and its implementing regulations set forth a number of conditions and limitations on the coverage of listed services and items, (42 U.S.C.A. § 1395k, 1395l, 1395x(v) (West 1983 & Supp. 1988)), exclude certain services and items from coverage (42 U.S.C.A. § 1395g (West 1983)), and specify several limits on what is characterized as the reimbursable "reasonable charge" for covered services and items (42 U.S.C.A. 1395u(b) (West Supp. 1988)). *See also* 42 C.F.R. 405.501 *et seq.* (1987). The Health Care Financing Administration(HCFA) has explained and clarified these criteria in the Part B Carrier's Manual, issued pursuant to the Secretary of Health and Human Services' (Secretary) interpretive rulemaking authority. *See* 5 U.S.C.A. § 553; 42 U.S.C.A. §§ 1302, 1395hh (West 1983 & Supp. 1988).

Among the statutory limitations on Part B coverage, 42 U.S.C.A. § 1395y(a)(1)(A) (West Supp. 1988) prohibits payment for medical services or items which, although within the general scope of coverage, are "not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of malformed body member." 42 C.F.R. § 405.310(k)(1) (1987). A seat lift chair may be covered as an item of "durable

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> The findings and decision of the Secretary after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the Secretary shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the Secretary, or any officer or employee thereof shall be brought under section 1331 or 1346 of title 28 to recover on any claim arising under this subchapter.

The plain language of this provision appears to say that *no* finding of fact or decision shall be reviewed. *See Bartlett v. Bowen*, 816 F.2d 695, 713 (D.C.Cir. 1987) (Bork, J., dissenting) ("there is no dispute that the judicial review provisions of the Medicare Act taken on their face, explicitly deny to any and all courts jurisdiction ...)".

medical equipment",[2] but only under circumstances where it is medically necessary under such criteria. Reimbursement is available only in those limited circumstances where a beneficiary has severe arthritis of the knees or hips, muscular dystrophy, or similar neuromuscular disease; where the chair is included in a physician's course of treatment and is likely to effect improvement or arrest deterioration of the patient's condition; and where the beneficiary would otherwise be bed or chair confined. Part B Carrier's Manual, Coverage Issues Appendix § 60.8 (1978). Accordingly, the seat lift chair may not be covered as a comfort or convenience item, but must be part of a course of treatment for a beneficiary who otherwise would be unable to arise and ambulate in order to improve or arrest deterioration of a severely arthritic condition.

The Secretary has delegated to the Part B Carrier the authority to determine whether a claimed service or item is medically necessary and is otherwise covered under Part B, and to fix the "reasonable charge" that may be paid for covered services and items. 42 U.S.C.A. § 1395u(a) (West Supp. 1988); 42 C.F.R. § 405.803, 421.200 (1987). In performing these responsibilities, the Carrier applies the coverage and reimbursement criteria prescribed by the enabling statute and the Secretary. The Carrier is reimbursed by the Secretary for costs of claim administration, and pays: (1) the charge for a comparable service or item applicable to the Carrier's own policy holders (42 U.S.C.A. § 1395u(b)(3)(B) (West Supp. 1988)); (2) the supplier's "customary charge" for the service or item during the "base year" that precedes the "fee screen" year, 42 U.S.C.A. § 1395u(b)(3)(F) (West Supp. 1988) or (3) the "prevailing" charge in the designated locality during the base year that precedes the fee screen year. *Id.*

The Secretary may also designate services or items that do not vary in quality among suppliers. For such items, the statute establishes a "lowest charge level" (LCL) limit upon the "reasonable charge" which can be imposed. Each Carrier submits for the item

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2. "Durable medical equipment" is defined as equipment that can withstand repeated use, primarily serves a medical purpose, is not useful in the absence of illness or injury and is appropriate for use in the home. 42 C.F. § 405.514(b)(1987).

and LCL set at the 25th percentile of actual Medicare charges in the locality. The statute does not confine the Carrier to any of the four "reasonable charge" standards ("comparable charge," "customary charge," "prevailing charge," or LCL). Instead, the Carrier may consider not only the four aforementioned fee screens, but also:

> Other factors that may be found necessary and appropriate with respect to a category of service to use in judging whether the charge is inherently reasonable. This includes special reasonable charge limits.

42 C.F.R. § 405.502(a)(7)(1987).

The regulations further state that are accorded "flexibility" in determining reasonable charges. 42 C.F.R. § 405.502(a) (1987). Carriers must "exercise [their] judgement based on factual data on the charges made by [suppliers] to patients generally and by other persons to the public in general and on special factors that may exist in individual cases." § 405.502(a)(10)(c) (1987). If the customary and prevailing methodology has yielded a result that is inherently unreasonable, the Carrier may use *any* available relevant information.[3]

Thus, the Carrier is given wide discretionary judgment to consider "inherent reasonableness" criteria under those circumstances where use of customary and prevailing charge data alone would result in unreasonable costs. The Secretary considers inherent reasonableness criteria under circumstances where the charges for the item in the locality are substantially out of line with charges elsewhere; where Medicare is the sole or primary source of payment for the item; where the charges do not reflect the influence of a competitive marketplace (i.e., the market is "dominated" by one or a few suppliers); where there have been sudden increases in charges that cannot be readily explained by normal economic factors such as inflation; where the charges are

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3. Because the inherent reasonableness criterion is available, the Secretary's decision need not conform to the LCL standards (the LCL methodology is only one of the alternatives available to the Secretary). Therefore, the court need not consider appellants' charge that the Secretary's seat lift policy did not meet the LCL guidelines.

substantially in excess of acquisition or production costs; or where charges for the item are substantially higher to Medicare beneficiaries than to others. Thus, under circumstances where the customary and prevailing charge methodology of the enabling statute has yielded a result that is not inherently reasonable, the Carrier may exercise its discretionary responsibility and use any available relevant information and apply reasonable assumptions in establishing a reasonable charge. Information the carrier may consider includes the supplier's acquisition or production costs, the charges of suppliers who service essentially a non-Medicare market, manufacturer's suggested retail prices, charges made by suppliers in other market areas, the Medicare allowance provided for the least expensive item that meets the patients' medical needs, as well as other impacting criteria that reasonable minds would consider in determining a "reasonable charge".[4]

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4. Following the Carrier's determination in the instant case, Congress amended 42 U.S.C.A. § 1395u(b)(8) (West Supp.1988) to require the Secretary, through regulations, to describe the factors to be applied in determining a "reasonable charge" where application of the standard reasonable charge methodology results in charges that are not inherently reasonable, along with the factors to be used in establishing a "reasonable charge" in such cases. On August 11, 1986, the Secretary amended his regulations to comply with the congressional promulgation. 42 C.F.R. § 405.502(a)(7), (g) (1986). The foregoing legislative and administrative enactments are of no consequence in the resolution of this appellate review; nor are the 1986 amendments to 42 U.S. C.A. § 1395ff (West Supp. 1988) which provide for limited administrative and judicial review of Part B payment determinations, effective for services and items furnished after January 1, 1987.

Any Part B beneficiary, physician or supplier accepting assignment, who is dissatisfied with a Carrier decision that a claimed item or service is not covered, or with a decision concerning the amount reimbursable for a covered item or service, is mandated an independent reconsideration by the Carrier and a nonadversarial, evidentiary hearing before a Carrier-appointed hearing officer. 42 C.F.R.§ 405.801 *et seq.* (1987). The beneficiary or supplier, who may be represented by counsel, may examine all evidence initially considered by the Carrier and present additional evidence and argument, produce and examine witnesses and file post-hearing statements in support of his position. 42 C.F.R. § 405.830, 405.870 (1987). The hearing officer's disposition must be in accord with all statutory and regulatory provisions as well as HFCA instructions, policy statements, and other interpretive authorities. 42 C.F.R. § 405.860 (1987). The disposition becomes a final order subject to reconsideration only by the hearing officer. 42 C.F.R. §§ 405.835, 405.841 (1987).

Prior to August 1985, the maximum reasonable charge allowable for seat lift chairs under the Medicare Part B Program in the state of Ohio was determined either on the basis of the "customary charge" fee screen (the amount a particular supplier charged medicare customers during the previous year), or on the basis of the "prevailing charge" fee screen (the 75th percentile of all customary charges). These screens in Ohio ranged from $1,150.00 to $2,262.00.

The record discloses that beginning in early 1984, a number of medical equipment suppliers, including Cincinnati-based Queen City Home Health Care, embarked upon a concentrated and widespread television advertising campaign promoting seat lift chairs in Ohio and other states. The promotion was directed to Medicare beneficiaries rather than to prescribing physicians and promoted seat lift chairs "at no cost, absolutely no cost" with a qualifying medical condition and supplemental insurance. Queen City mailed its preprinted prescription form, upon the telephone request of beneficiaries, to the beneficiary's physician for signature and delivered the "no cost" seat lift chair, and filed and assigned claims with Nationwide Mutual Insurance Company, the Ohio Part B Carrier.

During April 1985, while the Carrier's "Support Service Division" was compiling charged data for the April 1984-March 1985 base period necessary to calculate the prevailing charge level for services and items for the forthcoming 1986 fee screen year, it noticed a significant escalation in the number of seat lift chair claims, along with numerous complaints and inquiries from beneficiaries' physicians, members of Congress and the media concerning medical equipment suppliers, advertising, and the quality and cost of seat lift chairs. The Carrier's review disclosed that during the first calendar quarter of 1985, Queen City Home Health Care [Queen City] of Cincinnati alone billed $13 million in assigned Medicare claims, mostly for seat lift chairs; beneficiaries also initiated numerous complaints, most regarding the excessive cost of up to $2,400.00 per seat lift chair; comparable items were available from local sources at costs as low as $995.00 per chair.

In April, 1985, before the HCFA contacted Nationwide, its survey had reflected that seat lift chair sales increased from 276 in 1982 to 513 in 1983. The cost of chairs dropped to $1,695 from $2,132. However, during the April, 1984 to March, 1985 period, the number of chairs paid for by Medicare jumped to 11,504, from 513 in a comparable period a year earlier. Charges escalated from an average of $1,695 to $2,400. Because Queen City Home Health Care dominated three-fourths of the pertinent seat lift market, Queen City effectively determined the prevailing charge and the customary charge--both of which had increased dramatically over the previous year. The Carrier concluded that the increase failed to reflect the influence of a competitive market. Queen City's "prevailing charge" in particular was excessive--$2,400. Nationwide's review found that the prevailing charge level in Indiana was $1,168 and in Michigan, $1,295 and $1,716--far below the $2,400 prevailing charge in Ohio. Its investigation ultimately prompted it to conclude that further measures in addition to applying the standard reimbursement methodology were necessary to assure payment of only a "reasonable charge," and proposed three alternative measures: (1) subjecting seat lift chairs to the lowest charge level provisions; (2) limiting yearly increases in prevailing charge levels for durable medical equipment by an economic index; and (3) establishing an "inherently reasonable" charge, also referred to as a "Level III ceiling," for seat lifts and other durable medical equipment based on the lowest manufacturer's suggested retail price for the item.

After the Carrier had undertaken its review, the Health Care Financing Administration (HCFA) advised all regional Carriers to closely scrutinize seat lift chair claims. William Desmarais (Desmarais), Director of HCFA's Bureau of Eligibility, Reimbursement and Coverage, wrote to Regional Administrators of HCFA on May 30, 1985, advising Carriers that the reasonable charge for seat lift chairs should not exceed the least expensive alternative that satisfied the patients' needs. This letter was a "confirmation" of Nationwide's recommendation to establish a Level III ceiling. *See* Carruthers' Affidavit of September 24, 1986 at ¶ 15. The letter advised administrators to "take into account" catalogue prices

for seat lift chairs and noted that it would not be "inherently reasonable" to allow more than the catalogue price unless special medical justifications were present. The Desmarais memorandum advised each Regional Administrator to remind Carriers to review seat lift chair claims, and if necessary obtain additional medical evidence, to establish that a given chair satisfied the medical necessity criteria set forth in the Carrier's Manual and was not merely a personal comfort item. The review was necessary, he explained, because seat lift chair orders were being solicited by suppliers rather than originating with physicians, who were simply sent supplier-generated checklists for their signature. With respect to supplier charges, the Desmarais memorandum cited the "inherent reasonableness" criterion of 42 C.F.R. § 405.502(a)(7) and explained that under this criterion, charges could not exceed the allowance for the least expensive alternative that met a patient's medical needs and was available to beneficiaries. The Desmarais memorandum alluded to the catalogue prices of four seat lift chair models as "examples" of how Carriers could apply the inherent reasonableness criterion, and stated that "in this example" it would not be inherently reasonable to allow more than the charge for a standard model ($749.95), plus shipping, absent medical justification for more expensive models in individual cases.

In a subsequent memorandum to the Chicago HCFA Regional Administrator dated June 7, 1985, Desmarais stated that application of the inherent reasonableness criterion "should be considered" by Carriers in determining allowable charges for seat lift chairs and further observed that prior HCFA memoranda "were intended to increase Carrier awareness" of their longstanding authority to apply inherent reasonableness "and to give them [Carriers] examples of how this might be done." The memorandum specifically acknowledged HCFA's own lack of current authority to direct specific national "inherent reasonableness" limits which would be mandatory on Carriers, and noted instead that it was within the sole discretion of each individual Carrier to derive its own "inherent reasonableness" determination at its service level.

Subsequent to the two Desmarais memoranda, the Associate Regional Administrator for HCFA circulated a letter in June 1985 to all Carriers in the Chicago region (including Nationwide) discussing the review of seat lift chair claims and the determination of allowable reasonable charges. As with the Desmarais memoranda, the HCFA regional letter emphasized the Carriers' exclusive authority to determine "inherently reasonable" charges, and cited Sears as well as Montgomery Ward as an "example" of available sources of seat lift chairs that Carriers could utilize in determining if Medicare charges in their service areas were "inherently reasonable." The HCFA regional letter requested each Carrier to apply the inherent reasonableness criterion to its allowances, using the information provided, "as appropriate." Carriers were further requested to inform the regional office of their reasonable charge allowances and the basis for their determinations.

Following receipt of the HCFA regional letter, Nationwide, which previously had been reviewing charge data and other information to determine the reasonableness of seat lift chair charges, proceeded to derive its "inherently reasonable" charge for seat lift chairs. The HCFA regional letter had confirmed Nationwide's own prior proposal to establish an "inherently reasonable" charge based on its earlier conclusions that the Medicare prevailing charge level of $2,400, based on supplier charges during the April 1984-March 1985 base period, was excessive. In addition to the information previously considered, the Carrier's staff surveyed several sources of seat lift chairs including those suggested in the HCFA regional letter. Sciotec, Inc., a major manufacturer of durable medical equipment, advised Nationwide that its wholesale, or dealer list, price for a standard seat lift chair was $450, and furnished brochures.[5] Pride Health Care, Inc., another durable medical equipment, manufacturer, furnished a dealer price list indicating a dealer list price of $575 for a standard seat lift chair. A third manufacturer, Action Lift Chair, Inc., provided information indicating a dealer list price for a standard seat lift

5. Queen City, which furnished over 75 percent of the 11,504 seat lift chairs sold to Medicare beneficiaries in the April 1984—March 1985 base period, obtained its chairs at a wholesale cost of $450.

chair of $850 for one to three units, which decreased as additional units were purchased.

The Carrier's staff also contacted several national catalogue houses which disclosed that J.C. Penney and Spiegel did not sell durable medical equipment. Montgomery Ward advertised a seat lift chair in its Fall/Winter 1985 catalogue for $799.95 plus shipping. Sears offered a standard upright seat lift chair in its 1985/1986 Home Health Care "Specialog" for $749.95 plus shipping and assembly. The "Specialog" indicated that the entire chair (rather than just the seat) lifted in order to elevate an individual to a standing position. Nationwide concluded that the Sears standard chair would cost $869.51, including Ohio State sales tax of $53.10; shipping charges of $26.46, based upon weight, from a Sears store to a purchaser's home (Sears' personnel indicated that Sears paid shipping charges from the manufacturer to the store); and assembly charges of $40 based on an assumption that beneficiaries would not be able to assemble the chair.

Having considered the entire formidable compendium of statistical and comparative information collected during its comprehensive survey including: the pattern of Medicare claims and charges; the sudden rise in Medicare prevailing charges to excessive amounts; the noncompetitive nature of the Ohio Medicare market; Medicare charges in other states; manufacturers' suggested retail prices; wholesale costs; and the charges of national retail suppliers operating in a competitive, non-captive Medicare market, Nationwide was satisfied that the Sears basic seat lift chair satisfied a beneficiary's medical needs, was generally available to the beneficiary population, and at $869.51 was the least expensive alternative. It therefore concluded that $869.51 was an "inherently reasonable" charge.

Following its determination, the Carrier in July 1985 prepared a letter to HCFA stating the basis for its "inherently reasonable charge" for seat lift chairs within its assigned territory. On July 10, 1985, Nationwide issued a newsletter to suppliers advising them of its decision to implement an "inherently reasonable" charge screen of $869.51 for seat lift chairs, applicable to chairs furnished to beneficiaries on or after August 19, 1985. By letter

dated July 25, 1985, counsel for the newly formed "Association of Seat Lift Manufacturers" demanded that the Carrier immediately rescind its decision, asserting that Nationwide had failed to comply with the procedures for setting a "lowest charge level." When the Carrier did not rescind its decision, the association filed the instant action on August 12, 1985.

It is fundamental that "jurisdiction to review Medicare reimbursement determinations is available only as prescribed in the Medicare Act." *Riley Hospital & Benevolent Assoc. v. Bowen,* 804 F.2d 302, 304 (5th Cir. 1986) (citing *Heckler v. Ringer,* 466 U.S. 602, 104 S.Ct. 2013, 80 L. Ed. 2d 622 (1984)). "Appeals from adverse determinations on cost reimbursement under the Medicare Act may be had only as specifically set forth by Congress." *Riley Hospital,* 804 F.2d at 305.

In applying this principle, the Supreme Court in *United States v. Erika,* 456 U.S. 201, 102 S. Ct. 1650, 72 L. Ed. 2d 12 (1982), announced that the Medicare statute precluded federal court jurisdiction over determinations of the "amount of benefits" that were payable under Part B of the Act. The Court relied upon the "precisely drawn provisions" of 42 U.S.C.A. § 1395ff(b) (West 1983), which provided for hearings by the Secretary and judicial review regarding general eligibility to participate in Part A and Part B, and the amount of benefits payable under Part A, but "conspicuously" failed to authorize such administrative or judicial review of Part B payment determinations. 456 U.S. at 207-208, 102 S.Ct. at 1653-1654. The Court concluded that the "omission" provided "persuasive evidence" that Congress intended to foreclose judicial review of such determinations, and reasoned that the legislative history of § 1395ff(b) confirmed this conclusion. *Id.* at 208-211, 102 S. Ct. at 1654-1656. Accordingly, the Court decided that a Part B supplier's challenge to a Carrier's interpretation and application of the statutory and regulatory "reasonable charge" provisions, which the supplier cited as a basis for contesting the "amount of benefits," was precluded by the statute.

Subsequent to its decision in *Erika,* the Supreme Court affirmed this Circuit's decision in *Bowen v. Michigan Academy of*

Family Physicians, 476 U.S. 667, 106 S. Ct. 2133, 90 L. Ed. 2d 623 (1986) where it defined the test for preclusion of judicial review of Medicare, Part B payment determinations. In *Michigan Academy*, the Supreme Court mandated judicial review under circumstances where a supplier's claim could not be adjudicated at a Carrier "fair hearing" prescribed by the statute.[6] In that case, the court authorized judicial review for challenges to eight HCFA statutes, regulations or instructions and for challenges to the reasonable charge determination methodology employed by the Carrier in deriving a reasonable charge for services for durable medical equipment.

In the instant case, the appellants, as in *Erika*, 456 U.S. at 201, 102 S. Ct. at 1651, did not allege the invalidity of any statutory or regulatory provision. Appellants challenged only the derivation of the "reasonable charge" for seat lift chairs, charging that it was promulgated by the Carrier pursuant to specific instructions of HCFA, or in the alternative, that the methodology employed by Nationwide violated applicable HCFA regulations, thereby justifying judicial review. Appellants concisely defined the issue in the following language:

> If this Court finds that the instant case does not involve a challenge to HCFA's instructions, this Court must decide whether the instant case involves on the one hand a challenge to the reasonable charge determination methodology or on the other hand only a challenge to a benefit amount determination. Because appellants have alleged that the methodology employed by Nationwide violates HCFA regulations judicial review is permissible in the instant case.

In the instant case, Nationwide determined a "reasonable charge" of $869.51 for a seat lift chair, based on the "inherent reasonableness" criterion of 42 C.F.R. § 405.502(a)(7)(1987) and its consideration of numerous "other factors" under that criterion including, but not limited to, the retail price of a Sears seat lift chair. As the district court noted, plaintiffs did not challenge the

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6. See footnote 4.

Carrier's authority to establish allowable charges on an inherently reasonable basis, and did not challenge the validity of any other statutory or regulatory provision. Nor did plaintiffs challenge any instruction set forth in the Part B Carrier's Manual. Rather, as in *Erika,* the instant plaintiffs have alleged that the Carrier's specific "amount determination" was erroneous under the statute and regulations because it conflicted with other allegedly applicable regulatory criteria (the lowest charge level provisions) and failed to consider certain allegedly relevant factors (such as the number of seat lifts sold by Sears and the comparative overhead costs of Sears and other suppliers).

[1-4] On appeal, plaintiffs primarily asserted that the district court erred because "HCFA specifically *instructed* Nationwide to determine the reasonable charge for seat lift chairs ... on the basis of the Sears catalogue price." Plaintiffs also argued that even if the present case does not involve a challenge to HCFA regulations or instructions, jurisdiction is available on three alternate grounds. Initially they claimed that their challenge is to only the "methodology" employed by the Carrier, and, accordingly, is subject to review under *Michigan Academy.* Second, they suggested that even if their challenge can be judged at a Carrier "fair hearing," that challenge is not—in monetary terms—the "minor" or "trivial" one that was congressional focus in enacting § 1395ff. Finally, plaintiffs contended that this action involves a perspective challenge to the Carrier's "reasonable charge" determination by a group of manufacturers and suppliers, whereas Congress precluded review only of decisions on specific, individual retrospective claims.

A review of the record in its entirety, with particularity the Desmarais, the Gagel, and Stec memoranda and letters,[7] clearly reflects that HCFA did not "instruct" Nationwide to derive the allowable reasonable charge for seat lift chairs on the basis of the Sears catalogue price. The memoranda read in context were purely informational or advisory and specifically recognized that the

7. William Desmarais was Director of HCFA's Bureau of Eligibility, Reimbursements and Coverage; Barbara J. Gagel was Regional Administrator of HCFA's Region V and Judith Stec was Associate Regional Administrator of HCFA Region V during the time periods here in issue.

HCFA lacked the regulatory authority to unilaterally promulgate national "reasonable" charges for a particular item or service. The agency was merely carrying out its general oversight role in assuring that Carriers apply pertinent statutes, regulations, and instructions in making such determinations, and brought pertinent information to the Carrier's attention for use in carrying out these responsibilities. Plaintiffs erroneously equated HCFA's exercise of that responsibility with a specific "directive" to set the allowable reasonable charge at the level of mail order catalogue prices. However, the record disclosed that Nationwide began its review of seat lift charges *before* the HCFA issued its advisory memoranda. In deposition testimony, Nationwide attested that it did not consider the memoranda to be a directive to establish a charge based on the Sears catalogue price. Nationwide asserted that the HCFA memoranda were merely a "confirmation" of its pre-existing policy. Moreover, in July, 1986, Nationwide actually pushed for a broader application of the inherently reasonable criteria than the HCFA had recommended. Nationwide sought to apply the criteria to *all* medical products for which catalogue prices were available.

In short, the Carrier made an independent determination of the reasonableness of medicare charges for seat lifts after evaluation of numerous factors in addition to the Sears catalogue price recommended in the HCFA memoranda. That Nationwide ultimately concluded upon its independent evaluation that the Sears catalogue price represented an "inherently reasonable" charge does not mean that it did so at the specific "direction" of HCFA. Accordingly, the HCFA memoranda cannot be described as "instructions" or regulations and hence *Michigan Academy* is distinguishable.

Plaintiffs' first alternative argument is that the instant case involves the "method by which [Part B] amounts are to be determined" and that jurisdiction is, therefore, available under *Michigan Academy*. However, the Supreme Court's opinion in *Michigan Academy* concluded that challenges to statutes, regulations, and instructions prescribing Part B payment criteria, rather than challenges to the application of such criteria by Carriers in

making Part B "payment determinations," were the only type of challenge that could not be adjudicated in a Carrier fair hearing. Because the instant plaintiffs essentially disputed only Nationwide's application of the "inherent reasonableness" criterion in determining the reasonable charge for seat lifts rather than the validity of that criterion itself, their so-called "method" challenge is actually a challenge to an amount determination and *Erika,* rather than *Michigan Academy,* is controlling. *See Kuritzky v. Blue Shield of Western New York,* 850 F.2d 126 (2d Cir.1988) ("method" challenge is only reviewable if it involves rules, regulations and statutes and not the carriers' method of applying the regulations).

Nor is it significant that the "amount determination" at bar involves a large sum of money. Applicable authority suggests that judicial review over all Part B amount determinations is precluded. While Congress acted on the basis that Part B payments "*generally* were expected to be smaller," *see Erika,* 456 U.S. at 208, 102 S.Ct. at 1654, it in fact precluded review of *all* Part B payment determinations prior to January 1, 1987, rather than only those specific determinations judged on a case-by-case basis to be "minor" or "trivial." The 1986 legislation, which provides for judicial review (subject to amount in controversy requirements and several other restrictions) only with respect to services and items furnished on or after January 1, 1987, supports this interpretation of prior law. The 1986 legislation specifically precluded judicial review of Nationwide's reasonable charge determination for seat lift chairs fixed prior to January 1, 1987, while it authorized judicial review of those charges which were established after that date.

This court also rejects plaintiffs' argument that jurisdiction is available over "prospective challenges" to the Secretary's decision. In reaffirming *Erika* the Supreme Court in *Michigan Academy* drew no distinction between prospective challenges and challenges arising in the context of an individual claim, where both challenges are directed at the Carrier's "payment determination" rather than at the Secretary's regulations or instructions. Plaintiffs cannot contend that the Carrier's reasonable charge determination is subject to review simply because they filed their challenge

before the Carrier actually applied its determination to any individual claim.

Lastly, it is important to note that a Carrier fair hearing was available to adjudicate the validity of appellant's claims. A Part B supplier dissatisfied with a Carrier decision is entitled to an independent reconsideration by the Carrier and to a nonadversarial evidentiary hearing before a Carrier-appointed hearing officer. 42 C.F.R. § 405.801 *et seq* (1987). The supplier may be represented by legal counsel, may examine all evidence presented by the Carrier, may cross-examine witnesses, and may file post-hearing statements. The hearing officer must adhere to all statutes and regulations and the Carrier must follow the hearing officer's decision which may not be revised by the Carrier or HCFA.

Crucially, Queen City Home Health Care invoked a Carrier hearing to review Nationwide's determination as applied to its assigned claims. On March 2, 1987, the hearing officer affirmed Nationwide's determination after considering Queen City's evidence and arguments at length.

In light of the foregoing, the instant case is readily distinguishable from *Michigan Academy*. That decision was anchored in part upon the lack of a hearing:

> We conclude, therefore, that those matters which Congress did *not* leave to be determined in a "fair hearing" conducted by the carrier—including challenges to the validity of the Secretary's instructions and regulations—are not impliedly insulated from judicial review.

106 S.Ct. at 2140. Similarly distinguishable is the decision in *Medical Fund-Philadelphia Geriatric Center v. Heckler,* 804 F.2d 33 (3d Cir.1986). The Third Circuit instructed the lower court that "the district court must examine its jurisdiction over each claim on remand, as its jurisdiction depends on whether the claim lay outside the jurisdiction of the [Carrier] hearing officer." 804 F2d at 39. Accordingly, the existence of a hearing in the instant case significantly undercuts any argument for federal court jurisdiction. *See Kuritzky v. Blue Shield of Western New York,* 850 F.2d 126 (2d Cir.1988) (Congress meant the hearing officer to be the final ar-

biter of Part B amount determination claims and if a hearing is available, judicial review is unavailable).

In summary, appellees did not "instruct" the Carrier in any way; its memoranda were merely informational and advisory. Nor is the instant challenge one to the "methodology" of the determination since the challenges did not involve the *statutory or regulatory* method used to determine a rate. In the instant case, as in *Erika,* only implementation of a method, not the method itself, was at issue.

Since a hearing was accorded to the instant claimant, *Michigan Academy* does not require this court to exercise jurisdiction. Accordingly, the decision of the lower court is AFFIRMED.

UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF OHIO EASTERN DIVISION

ASSOCIATION OF SEAT LIFT MANUFACTURERS, A TRADE ASSOCIATION, et al.,

Plaintiffs

v.

OTIS R. BOWEN, Secretary of Health and Human Services, et al.,

Defendants

LAMBROS, DISTRICT JUDGE

No. C 85-2253

MEMORANDUM OPINION AND ORDER.

Plaintiffs in this action seek an order setting aside the administrative determination that $869.51 is the allowable "reasonable charge" for a seat lift chair under the Medicare Part B program in Ohio.

Part B of the Medicare program is a federally subsidized health insurance system which covers certain medical expenses. For some individuals, particularly those with debilitating conditions of the hips or knees, the cost of a seat lift chair may be covered. Determinations with regard to the availability and amount of reimbursement are made by, in this case, Nationwide Mutual Insurance Company (the "carrier"), acting as the agent of the Secretary of Health and Human Services, pursuant to contract. Reimbursement is made to the Part B enrollee, or his assignee in the case of medical providers that accept assignment.

In establishing the allowable "reasonable charge" for a medical service, the carrier is guided by the flexible criteria set forth in 42 C.F.R. § 405.502. Often, the reasonable charge for a given service is the "customary" or "prevailing" charge. See 42 C.F.R. § 405.502(a)(1) and (2). But the carrier is also authorized to consider "[o]ther factors that may be found necessary and appropriate with respect to a specific item of service to use in judging whether the charge is inherently reasonable." 42 C.F.R. § 402.502(a)(7). In the case at bar, the carrier eschewed the standard methods of

determining a "reasonable charge," and established what it deemed an inherently reasonable charge based on the "least expensive alternative," a seat lift chair advertised in the Sears & Roebuck catalog. The carrier calculated that, factoring in the costs of shipping, assembly, and tax, the Sears chair was available for $869.51. Plaintiffs request that determination of reasonable charge be set aside as unlawful.

Unquestionably, a carrier is invested with some discretion in determining reasonable charges for Medicare Part B reimbursement purposes. *See* 42 C.F.R. § 405.502(c) and (d). The defendants herein maintain that the discretionary reasonable charge determination at issue is not subject to judicial review. Previously, this Court denied the government's motion to dismiss for lack of subject matter jurisdiction. In so ruling, the Court relied on the opinion of the Court of Appeals in *Michigan Academy of Family Physicians v. Blue Cross and Blue Shield of Michigan*, 757 F.2d 91 (6th Cir. 1985). Subsequently, however, that case was reviewed (and affirmed) by the Supreme Court, *sub nom. Bowen v. Michigan Academy of Family Physicians,* 476 U.S. ___ , 106 S. Ct. 2133, 90 L.Ed. 2d 623 (1986). Based upon the decision of the Supreme Court, defendants have again moved for dismissal or summary judgment on the jurisdictional issue.

The respondents in *Michigan Academy* challenged the validity of 42 C.F.R. § 405.504(b), a regulation promulgated under Part B of the Medicare program. The regulation prescribed a method by which physicians' services could be valued at different rates.

In disscussing the scope of judicial review of administrative action, the Supreme Court reiterated its view that there is no judicial review of determinations concerning the amount of Medicare Part B payments. See also *United States v. Erika, Inc.,* 456 U.S. 201 (1982). The Court drew a distinction, however, between the calculation of the amount payable and the method by which such amounts are determined. Jurisdiction in *Michigan Academy* was upheld because "an attack on the validity of a regulation is not the kind of administrative action that we described in *Erika* as an 'amount determination' which decides 'the amount of the

Medicare payment to be made on a particular claim' and with respect to which the Act impliedly denies judicial review." 106 S.Ct. at 2139, 90 L.Ed. 2d at 632. The Court summarized its conclusions as follows:

> Careful analysis of the governing statutory provisions and their legislative history thus reveals that Congress intended to bar judicial review only of determinations of the amount of benefits to be awarded under Part B. Congress delegated this task to carriers who would finally determine such matters in conformity with the regulations and instructions of the Secretary. We conclude therefore, that those matters which Congress did *not* leave to be determined in a "fair hearing" conducted by the carrier--including challenges to the validity of the Secretary's instructions and regulations--are not impliedly insulated from judicial review by 42 U.S.C. § 1395ff.

106 S.Ct. at 2140, 90 L.Ed. 2d at 633.

Resolution of the jurisdictional issue in the case at bar turns, therefore, upon a characterization of the matter in dispute. This presumes that method and calculation are easily differentiated; but the distinction is not always so clear, because a calculation generally entails some underlying method. *Plaintiffs have attempted to label certain internal memoranda* as *"the Secretary's instructions,"* but nonetheless it appears evident to this Court that the real nub of the comtroversy herein is the carrier's amount determination, not its method. In fact, plaintiffs concede in their "Memorandum of Points and Authorities in Support of Plaintiffs' Cross Motion for Summary Judgement," at 11-12, "Plaintiffs cannot and, of course, do not challenge the Defendants [sic] ability to determine a maximum reasonable charge on an 'inherently reasonable' basis."

The present controversy involves a determination of the amount of benefits under Medicare Part B. It is not a challenge to the statute or regulations relevant to the Medicare program. Accordingly, it falls outside the scope of judicial review. *See Michigan*

Academy, supra. Defendants' motion to dismiss for want of jurisdiction is granted.

This action is dismissed and terminated.

IT IS SO ORDERED.

/s/_____
Thomas D. Lambros
United States District Judge

DATED:1/29/87

UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF OHIO EASTERN DIVISON

ASSOCIATION OF SEAT LIFT MANUFACTURERS, A TRADE ASSOCIATION, et al.,

Plaintiffs

v.

OTIS R. BOWEN, Secretary of Health and Human Services, et al.,

Defendants

LAMBROS, DISTRICT JUDGE

No. C 85-2253 JUDGMENT

In accordance with the memorandum opinion and order of this date in the above-captioned case, defendants' motion to dismiss the amended complaint is hereby granted.

This action is dismissed and terminated.

IT IS SO ORDERED.

/s/_____
Thomas D. Lambros
United States District Judge

DATED:1/29/87

28 U.S.C.A. § 1331 (West Supp. 1988)

§ 1331. Federal question

The district courts shall have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States.

42 U.S.C.A. § 405 (West 1983)
EVIDENCE, PROCEDURE, AND CERTIFICATION FOR PAYMENTS

(h) Finality of Secretary's decision

The finding and decision of the Secretary after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the Secretary shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the Secretary, or any officer or employee thereof shall be brought under section 1331 or 1346 of Title 28 to recover on any claim arising under this subchapter.

42 U.S.C.A. § 1395ff (West 1983 & Supp. 1985)

§ 1395ff. Determinations of Secretary

(a) Entitlement to and amount of benefits

The determination of whether an individual is entitled to benefits under part A or part B of this subchapter, and the determination of the amount of benefits under part A supchapter, shall be made by the Secretary in accordance with regulations prescribed by him.

(b) Appeal by individuals

(1) Any individual dissatisfied with any determination under subsection (a) of this section as to--

(A) whether he meets the conditions of section 426 or section 426a of this title, or

(B) whether he is eligible to enroll and has enrolled pursuant to the provisions of part B of this subchapter or section 1395i-2 of this title, or

(C) the amount of benefits under part A of this subchapter (including a determination where such amount is determined to be zero)

shall be entitled to a hearing thereon by the Secretary to the same extent as is provided in section 405(b) of this title and to judicial review of the Secretary's final decision after such hearing as is provided in section 405(g) of this title.

(2) Notwithstanding the provisions of subparagraph (C) of paragraph (1) of this subsection, a hearing shall not be available to an individual by reason of such subparagraph (C) if the amount in controversy is less than $100; nor shall judicial review be available to an individual by reason of such subparagraph (C) if the amount in controversy is less than $1,000.

(c) Appeal by institutions or agencies

Any instution or agency dissatisfied with any determination by the Secretary that it is not a provider of services, or with any determination described in section 1395cc(b)(2) of this title, shall be entitled to a hearing thereon by the Secretary (after reasonable notice and opportunity for hearing) to the same extent as is provided in section 405(b) of this title, and to judicial review of the Secretary's final decision after such hearing as is provided in section 405(g) of this title.

42 U.S.C.A. § 1395ff (West Supp. 1988)

§ 1395ff. Determinations of Secretary

(a) Entitlement to and amount of benefits

The determination of whether an individual is entitled to benefits under part A or part B of this subchapter, and the determination of the amount of benefits under part A or part B of this subchapter, and any other determination with respect to a claim for benefits under part A of this subchapter or a claim for benefits with respect to home health services under part B of this subchap-

ter shall be made by the Secretary in accordance with regulations prescribed by him.

(b) Appeal by individuals

(1) Any individual dissatisfied with any determination under subsection (a) of this section as to --

(A) whether he meets the conditions of section 426 or section 426a of this title, or

(B) whether he is eligible to enroll and has enrolled pursuant to the provisions of part B of this subchapter or section 1395i-2 of this title,

(C) the amount of benefits under part A or part B of this subchapter (including a determination where such amount is determined to be zero), or

(D) any other denial (other than under part B of subchapter XI of this chapter) of a claim for benefits under part A of this subchapter or a claim for benefits with respect to home health services under part B of this subchapter,

shall be entitled to a hearing thereon by the Secretary to the same extent as is provided in section 405(b) of this title and to judicial review of the Secretary's final decision after such hearing as is provided in section 405(g) of this title. Sections 406(a), 1302, and 1395hh of this title shall not be construed as authorizing the Secretary to prohibit an individual from being represented under this subsection by a person that furnishes or supplies the individual, directly or indirectly, with services or items solely on the basis that the person furnishes or supplies the individual with such a service or item. Any person that furnishes services or items to an individual may not represent an individual under this subsection with respect to the issue described in section 1395pp(a)(2) of this title unless the person has waived any rights for payment from the beneficiary with respect to the services or items involved in the appeal. If a person furnishes services or items to an individual and represents the individual under this subsection, the person may not impose any financial liability on such individual in connection with such representation.

(2) Notwithstanding paragraph (1)(C) and (1)(D), in the case of a claim arising--

(A) under part A, a hearing shall not be available to an individual under paragraph (1)(C) and(1)(D) if the amount in controversy is less than $100 and judicial review shall not be available to the individual under that paragraph if the amount in controversy is less than $1,000; or

(B) under part B, a hearing shall not be available to an individual under paragraph (1)(C) and (1)(D) if the amount in controversy is less than $500 and judicial review shall not be available to the individual under that paragraph if the aggregate amount in controversy is less than $1,000.

In determining the amount in controversy, the Secretary, under regulations, shall allow two or more claims to be aggregated if the claims involve the delivery of similar or related services to the same individual or involve common issues of law and fact arising from services furnished to two or more individuals.

(3) Review of any national coverage determination under section 1395y(a)(1) of this title respecting whether or not a particular type or class of items or services is covered under this subchapter shall be subject to the following limitations:

(A) Such a determination shall not be reviewed by any administrative law judge.

(B) Such a determination shall not be held unlawful or set aside on the ground that a requirement of section 553 of Title 5 or section 1395hh(b) of this title, relating to publication in the Federal Register or opportunity for public comment, was not satisfied.

(C) In any case in which a court determines that the record is incomplete or otherwise lacks adequate information to support the validity of the determination, it shall remand the matter to the Secretary for additional proceedings to supplement the record and the court may not determine that an item or service is

covered except upon review of the supplemented record.

(4) A regulation or instruction which relates to a method for determining the amount of payment under part B and which was initially issued before January 1, 1981, shall not be subject to judicial review.

(5) In an administrative hearing pursuant to paragraph (1), where the moving party alleges that there are no material issues of fact in dispute, the administrative law judge shall make an expedited determination as to whether any such facts are in dispute and, if not, shall determine the case expeditiously.

42 U.S.C.A. § 1395ii (West Supp. 1988)

§ 1395ii. Application of certain provisions of subchapter II

The provisions of sections 406 and 416(j) of this title, and of subsections (a), (d), (e), (h), (i), (j), (k), and (l) of section 405 of this title, shall also apply with respect to this subchapter to the same extent as they are applicable with respect to subchapter II of this chapter.

5 U.S.C.A. § 706 (West 1977)

§ 706. Scope of review

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall --

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action, findings, and conclusions found to be --

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

42 C.F.R. § 405 (1987)

Health Care Financing Administration, HHS § 405.501

Subpart E--Criteria for Determination of Reasonable Charges; Reimbursement for Services of Hospital Interns, Residents, and Supervising Physicians

§405.501 Determination of reasonable charges.

(a) Except as specified in paragraph (b) of this section, Medicare pays no more for Part B medical and other health services than the "reasonable charge" for such service. The reasonable charge is determined by the carriers (subject to any deductible and co-insurance amounts as specified in §§410.152 and 410.160 of this chapter).

(b) part B of the Medicare pays on the basis of "reasonable cost" (see Part 413 of this chapter) for certain institutional services, certain services furnished under arrangements with institutions, and services furnished by entities that elect to be paid on a

cost basis (including health maintenance organizations, rural health clinics, and end-stage renal disease facilities).

(c) Carriers will determine the reasonable charge on the basis of the criteria specified in § 405.502, and the customary and prevailing charge screens in effect when the service was furnished. (Also see §§ 405.480 through 405.482 and §§405.550 through 405.557, which pertain to the determination of reimbursement for services performed by hospital-based physicians.) However, when services are furnished more than 12 months before the beginning of the fee screen year (January 1 through December 30) in which a request for payment is made, payment is based on the customary and prevailing charge screens in effect for the fee screen year that ends immediately preceding the fee screen year in which the claim or request for payment is made.

§405.502 Criteria for determining reasonable charges.

(a) *Criteria.* The law allows for flexibility in the determination of reasonable charges to accommodate reimbursement to the various ways in which health services are furnished and charged for. The criteria for determining what charges are reasonable include:

(1) The customary charges for similar services generally made by the physician or other person furnishing such services.

(2) The prevailing charges in the locality for similar services.

(3) In the case of physicians' services, the prevailing charges for such services for fiscal year 1973 adjusted to reflected the cumulative economic index since calendar year 1971 but only if the charges so determined are not more than the prevailing charges determined under § 405.504(a)(2). The data used in determining the cumulative economic index should reflect changes in expenses of physicians' office practice and in general earnings levels.

(4) In the case of medical services, supplies, and equipment that are reimbursed on a reasonable charge basis (excluding physicians' services), the inflation-indexed charge as determined under §405.509.

(5) [Reserved]

(6) In the case of medical services, supplies, and equipment (including equipment servicing) that the Secretary judges do not generally vary significantly in quality from one supplier to another, the lowest charge levels at which such services, supplies, and equipment are widely and consistently available in a locality.

(7) Other factors that may be found necessary and appropriate with respect to a category of service to use in judging whether the charge is inherently reasonable. This includes special reasonable charge limits (which may be either upper or lower limits) established by HCFA or a carrier if it determines that the standard rules for calculating reasonable charge set forth in this subpart result in grossly deficient or excessive charges. The determination of these limits is described in paragraph (g) of this section.

(8) In the case of laboratory services billed by a physician but performed by an outside laboratory, the payment levels established in accordance with the criteria stated in § 405.515.

(9) Except as provided in paragraph (a)(10) of this section, in the case of services of assistants at surgery as defined in § 405.580 in teaching and non-teaching settings, charges that are not more than 20 percent of the prevailing charge in the locality, adjusted by the economic index, for the surgical procedure performed by the primary surgeon.

(10) In the case of services of assistants at surgery that meet the exception under § 405.580(c)(2) or (3) because the physician is performing a unique, necessary, specialized medical service in the total care of a patient during surgery, reasonable charges consistent with prevailing practice in the carrier's service area rather than the special assistant at surgery rate.

(b) *Comparable services limitation.* The law also specifies that the reasonable charge cannot be higher than the charge applicable for a comparable service under comparable circumstances to the carriers' own policyholders and subscribers.

(c) *Application of criteria.* In applying these criteria, the carriers are to exercise judgment based on factual data on the char-

ges made by physicians to patients generally and by other persons to the public in general and on special factors that may exist in individual cases so that determinations of reasonable charge are realistic and equitable.

(d) *Responsibility of Administration and carriers.* Determinations by carriers of reasonable charge are not reviewed on a case-by-case basis by the Health Care Financing Administration, although the general procedures and performance of functions by carriers are evaluated. In making determinations, carriers apply the provisions of the law under broad principles issued by the Health Care Financing Administration. These principles are intended to assure overall consistency among carriers in their determinations of reasonable charge. The principles in §§405.503 through 405.507 establish the criteria for making such determinations in accordance with the statutory provisions.

(e) *Determination of reasonable charges under the End-Stage Renal Disease (ESRD) Program--(1) General.* Reasonable charges for renal-related items and services (furnished in connection with transplantation or dialysis) must be related to costs and allowances that are reasonable when the treatments are furnished in an effective and economical manner.

(2) *Nonprovider (independent) dialysis facilities.* Reasonable charges for renal-related items and services furnished before August 1, 1983 must be determined related to costs and charges prior to July, 1973, in accordance with the regulations at § 405.541. Items and services related to outpatient maintenance dialysis that are furnished after that date are paid for in accordance with §§ 405.544 and 413.170 of this chapter.

(3) *Provider services and (hospital-based) dialysis facilities.* Renal-related items and services furnished by providers, or by ESRD facilities based in hospitals, before August 1, 1983 are paid for under the provider reimbursement provisions found generally in Part 413 of this chapter. Items and services related to outpatient maintenance dialysis that are furnished after that date are paid for in accordance with §§ 405.544 and 413.170 of this chapter.

(4) *Physicians' services.* Reasonable charges for renal-related physicians' services must be determined considering charges made for other services involving comparable physicians' time and skill requirements, in accordance with regulations at §§ 405.542 and 405.543.

(5) *Health maintenance organizations (HMOs).* For special rules concerning the reimbursement of ESRD services furnished by risk-basis HMOs, or by facilities owned or operated by or related to such HMOs by common ownership or control, see §§ 405.2042(b)(14) and 405.2050(c).

(f) *Determining charge payments for certain physicians' services furnished in outpatient settings--(1) General rule.* When physician services of the type routinely furnished in physicians' office are furnished in outpatient settings, carriers will determine the reasonable charge for those services by applying the limits described in paragraph(f)(4) of this section. As used in this paragraph (f), "outpatient settings" means hospital outpatient departments, clinics and emergency rooms, and comprehensive outpatient rehabilitation facilities (CORFs).

(2) *Services covered by limits.* The carrier will establish a list of services routinely provided in physicians' office in the area. The carrier has the discretion to determine which professional services are routinely provided in physicians' offices, based on current medical practice in the area. Listed below are some examples of routine services provided by office-based physicians.

Examples

Review of recent history, determination of blood pressure, ausculation of heart and lungs, and adjustment of medication is essential hypertension.

Brief history and examination, and initiation of diagnostic and treatment programs.

Treatment of an acute respiratory infection.

(3) *Services excluded from limits.* The limits established under this paragraph will not apply to:

(i) Services furnished in a rural health clinic.

(ii) Surgical services furnished in an ambulatory setting.

(iii) Services provided in a hospital emergency room that are necessary to prevent the death or serious impairment of the health of the individual.

(iv) Services provided by physicians who are compensated by or through the hospital and whose services are reimbursed on a compensation related charge basis as specified in 42 CFR 405.485; or

(v) Anesthesiology services and diagnostic and therapeutic radiology services.

(4) *Methodology for developing limits. (i) Development of a charge base.* The carrier will establish a charge base for each service identified as a routine office-based physician service. The charge base will consist of the prevailing charge in the locality for each such service adjusted by the economic index. The carrier will use the prevailing charges that apply to services by nonspecialists in office practices in the locality in which the hospital is located.

(ii) *Calculation of the outpatient limits.* The carrier will calculate the charge limit for each service by multiplying the charge base amount for each service by .60.

(5) *Application of limits.* The reasonable charge for physicians' services of the type described in paragraph (f)(2) of this section that are furnished in a hospital outpatient setting will be the lowest of the actual charges, the customary charges in accordance with § 405.503, the prevailing charges applicable to these services in accordance with § 405.504, or the charge limits calculated in paragraph (f)(4)(ii) of this section.

(g) *Determination of reasonable charges in special circumstances.* HCFA or a carrier may establish special reasonable charge limits for a category of service if it determines that the standard rules for calculating reasonable charges set forth in this subpart result in grossly deficient or excessive charges. The limit on the reasonable charge is an upper limit to correct a grossly excessive charge or a lower limit to correct a grossly deficient charge. The limits are either a specific dollar amount, or are based on a

special method to be used in determining reasonable charges to be allowed.

(1) *Application--(i) Grossly excessive charges.* HCFA or a carrier may make a determination that the standard rules for calculating reasonable charges set forth in this subpart result in grossly excessive charges. Examples of the circumstances which may result in grossly excessive charges include, but are not limited to the following:

(A) The marketplace is not competitive.

(B) Medicare is the primary source for payment.

(C) The charges involve the use of new technology for which an extensive charge history does not exist.

(D) The charges do not reflect changing technology, increased facility with that technology, or changes in acquisition or supplier costs.

(E) Prevailing charges in a locality are grossly in excess of prevailing charges in other localities.

(F) Charges are grossly in excess of acquisition or production costs.

(ii) *Grossly deficient charges.* HCFA or a carrier may make a determination that the standard rules for calculating reasonable charges set forth in this subpart result in grossly deficient charges. Examples of the circumstances which may result in grossly deficient charges include, but are not limited to the following:

(A) Changing technology substantially increases resource requirements.

(B) There has been a substantial and sudden increase in acquisition or production costs.

(2) *Factors considered.* In establishing a limit, HCFA or a carrier considers the available information that is relevant to the category of service and establishes a reasonable limit that is realistic and equitable. The factors to be considered in establishing a specific dollar amount or special method may include:

(i) *Price markup.* This is the relationship between the retail and wholesale prices or manufacturer's costs of a category of ser-

vice. If information on a particular category of service is not available. HCFA or a carrier may consider the markup on similar services and information on general industry pricing trends.

(ii) *Differences in charges.* HCFA or a carrier may consider the differences in charges to non-Medicare and Medicare patients or to institutions and other large volume purchasers.

(iii) *Costs.* HCFA or a carrier may consider data on acquisition or production costs.

(iv) *Utilization.* HCFA or a carrier may impute a reasonable rate of use for a category of service and consider unit costs based on efficient utilization.

(v) *Charges in other localities.*

(vi) *Other relevant factors.*

(3) *Publication of national limits.* HCFA publishes in the FEDERAL REGISTER a notice of a proposed and final special reasonable charge limit before the limit is adopted. The notice sets forth in the FEDERAL REGISTER the criteria and circumstances, if any, under which a carrier may grant an exception to the limit.

(4) *Carrier level limits.* After September 10, 1986, a carrier proposing to establish a generally applicable special reasonable charge limit must inform the affected suppliers or physicians of the factors considered in establishing the limit as described in paragraphs (g)(1) and (2) of this section and solicit comments. After evaluating the comments received, the carrier must inform the affected suppliers or physicians of any final limit established. The limit is effective for services furnished no fewer than 30 days after the date of the carrier's notification.

§ 405.511 Reasonable charges for medical services, supplies, and equipment.

(a) *General rule.* (1) A charge for any medical service, supply, or equipment (including equipment servicing) that in the judgment of HCFA generally does not vary significantly in quality from one supplier to another (and that is identified by a notice published in the FEDERAL REGISTER) may not be considered reasonable if it exceeds:

(i) The customary charge of the supplier (see § 405.503);

(ii) The prevailing charge in the locality (see § 405.504);

(iii) The charge applicable for a comparable service and under comparable circumstances to the policyholders or subscribers of the carrier (see § 405.508);

(iv) The lowest charge level at which the item or service is widely and consistently available in the locality (see paragraph (c) of this section); or

(v) The inflation-indexed charge, as determined under §405.509, in the case of medical services, supplies, and equipment that are reimbursed on a reasonable charge basis (excluding physicians' services).

(2) In the case of laboratory services, paragraph (a)(1) of this section is applicable to services furnished by physicians in their offices, by independent laboratories (see §405.1310(a)) and to services furnished by a hospital laboratory for individuals who are neither inpatients nor outpatients of a hospital. Allowance of additional charges exceeding the lowest charge level can be approved by the carrier on the basis of unusual circumstances or medical complications in accordance with § 405.506.

(b) *Public notice of items and services subject to the lowest charge level rule.* Before the Secretary determines that lowest charge levels should be established for an item or service, notice of the proposed determination will be published with an opportunity for public comment. The descriptions or specifications of items or services in the notice will be in sufficient detail to permit a determination that items or services conforming to the descriptions will not vary significantly in quality.

(c) *Calculating the lowest charge level.* The lowest charge level at which an item or service is widely and consistently available in a locality is calculated by the carrier in accordance with instructions from HCFA as follows:

(1) *For items or services furnished on or before December 31, 1986.*

(i) A lowest charge level is calculated for each identified item or service in January and July of each year.

(ii) The lowest charge level for each identified item or service is set at the 25th percentile of the charges (incurred or submitted on claims processed by the carrier) for that item or service, in the locality designated by the carrier for this purpose, during the second calendar quarter preceding the determination date. Accordingly, the January calculations will be based on charges for the July through September quarter of the previous calendar year, and the July calculations will be based on charges for the January through March quarter of the same calendar year.

(2) F*or items or services furnished on or after* January 1, 1987.

(i) A lowest charge level is calculated for each identified item or service in January of each year.

(ii) The lowest charge level for each identified item or service is set at the 25th percentile of the charges (incurred or submitted on claims processed by the carrier) for that item or service, in the locality designated by the carrier for this purpose, during the 3-month period of July 1 through September 30 preceding the fee screen year (January through December 31) for which the item or service was furnished.

(3) *Lowest charge levels for laboratory services.* In setting lowest charge levels for laboratory services, the carrier will consider only charges made for laboratory services performed by physicians in their offices, by independent laboratories which meet coverage requirements, and for services furnished by a hospital laboratory for individuals who are neither inpatients nor outpatients of a hospital.

(d) *Locality.* Subject to the approval of the Secretary, the carrier may designate its entire service area as the locality for purposes of this section, or may otherwise modify the localities used for calculating prevailing charges. (The modified locality for an item or service will also be used for calculating the prevailing charge for that item or service.)

42 C.F.R. §405.820 (1987)

§405.820 Right to a hearing

(a) *General.* Any party designated in §405.822 shall be entitled to a hearing after a review determination has been made by the carrier if the amount in controversy is $100 or more as determined in accordance with paragraph (b) of this section when such party files a written request for a hearing.

42 C.F.R. § 405.860 (1987)

§ 405.860 Authority of the hearing officer.

The hearing officer in exercising the authority to conduct a hearing under section 1842(b)(3)(C) of the Act is to comply with all the provisions of title XVIII of the Act and regulations issued thereunder, as well as with policy statements, instructions and other guides issued by the Health Care Financing Adminstration in accordance with the Secretary's agreement with the carriers.

MEDICARE CARRIERS MANUAL § 12016.A

12016. HEARING OFFICER

A. *Authority.* -- The HO occupies a significant position in the administrative appeals process. Authority of the HO is limited to the extent that he must comply with all provisions of title XVIII of the Act and regulations issued thereunder, as well as with HCFA rulings, general instructions and other guides issued by HCFA. The HO may not overrule the provisions of the law or interpret them in a way different than HCFA does when he disagrees with their intent; nor may he use hearing decisions as a vehicle for commenting upon the legality, constitutional or otherwise, of any provision of the Act or regulations relevant to the Medicare program. (See § 12022B regarding carrier's effectuation of the HO decision.)